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09/801,276	03/07/2001	Ulrich Haueter	14018	5513

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MINNEAPOLIS, MN 55402-1498

EXAMINER

JEFFERY, JOHN A

ART UNIT	PAPER NUMBER
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3742

DATE MAILED: 06/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/801,276

Applicant(s)

HAUETER ET AL.

Examiner

John A. Jeffery

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-33 is/are pending in the application.
- 4a) Of the above claim(s) 13-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 20 March 2003 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Objections*

Claims 1-10 and 12 are objected to because of the following informalities:

Claim 1: In line 3, "cooperably" is misspelled.

Appropriate correction is required.

### *Claims Elected by Original Presentation*

Newly submitted claims 13-33 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The inventions embodied by claims 13-21<sup>1</sup> and claims 1-10, 12 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) the subcombination has utility by itself or in other combinations. (MPEP 806.05(c)). In the instant case, the combination as claimed (health monitoring system) does not require the particulars of the subcombination as claimed (module) because the broadest combination claim (claim 13) does not, *inter alia*, require glucose concentration measurement, means for operably coupling a sensor to the module, etc. The subcombination has separate utility such as a computer interface for a variety of sensed body fluid characteristics.

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<sup>1</sup> Although newly-added claims 14-21 depend from claim 1, claims 14-21 are presumed to depend from claim 13 in view of their scope and content. Also, a comparison of the preamble of newly added claim 12 ("[t]he module as set forth in claim 1" -- consistent with claim 1) with the preambles of claims 14-21 ("[t]he health monitoring system as set forth in claim 1" -- inconsistent with claim 1) further suggests claims 14-21 were intended to depend from claim 13.

The inventions embodied by claims 28-33 and claims 1-10, 12 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) the subcombination has utility by itself or in other combinations. (MPEP 806.05(c)). In the instant case, the combination as claimed (system for monitoring glucose concentrations) does not require the particulars of the subcombination (module) as claimed because the broadest combination claim (claim 28) does not, *inter alia*, require the sensor being operably coupleable to the person. The subcombination has separate utility such as a computer interface for a variety of sensed body fluid characteristics.

The inventions embodied by claims 22-27 and claims 1-10, 12 are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP 806.05(e)). In this case, (1) the process as claimed can be practiced by another and materially different apparatus such as immersing the sensor in a container of body fluid, not necessarily operably coupling the sensor to the person. Moreover, the apparatus as claimed can be used to practice another and materially different process such as implanting the sensor to continually contact the body fluid, not necessarily first obtaining a fluid sample from the person, or displaying glucose concentration data on a computing device as required by the broadest method claim.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 13-33 are withdrawn from consideration as being directed to a nonelected invention. See 37 CFR 1.142(b) and MPEP 821.03.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 6, and 8-10 are rejected under 35 USC 102(b) as being anticipated by EP98592. The scope and breadth of the claims did not preclude EP98592 who discloses a blood glucose measurement "module" 2 including (1) means for electronic communication between the "module" 2 and "computer" 4, and (2) means for coupling a sensor 13 to the module 2. See Figs. 1 and 3 and P. 7, line 15 - P. 8, line 18. The sensor is coupleable to the person and to the module 2. The glucose concentration is wirelessly communicated to the computer 4 via radio transmitter 11.

Claims 1, 2, 4, and 6 are rejected under 35 USC 102(b) as being anticipated by Garcia et al (US4637403). Garcia et al (US4637403) discloses a glucose monitoring module 100 for interfacing with computer 114 (note plug 118). A sensor 12 is wirelessly coupled to the module via optical means.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP98592 or Garcia et al (US4637403) in view of Fischell (US4494950). The claims differ from the previously cited prior art in calling for the module to include a memory to store the measurement value. Providing data storage means in a measurement module which is wirelessly linked to a sensor module is conventional and well known in the art as evidenced by Fischell (US4494950) noting storage means 93. In view of Fischell (US4494950), it would have been obvious to one of ordinary skill in the art to provide a memory to store measurement values in the previously described apparatus so that the values could be retained as needed for display and/or comparison purposes.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP98592 or Garcia et al (US4637403) in view of Usala (US5776324). The claim differs from the previously cited prior art in calling for a hormone level sensor. The use of biosensors to

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detect either glucose or hormone levels is conventional and well known in the art as evidenced by Usala (US5776324) noting col. 7, lines 40-51. As noted in col. 6, lines 28-48, such hormones include biological substances secreted by certain tissues. In view of Usala (US5776324), it would have been obvious to one of ordinary skill in the art to provide a capability to detect hormones in the previously described apparatus so that biological substances secreted by certain tissues could be detected thereby detecting biological substances in addition to blood glucose levels.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP98592 or Garcia et al (US4637403) in view of Wong et al (US5758643). The claim differs from the previously cited prior art in calling for a temperature sensor. Providing a temperature sensor in conjunction with a blood glucose sensor is conventional and well known in the art as evidenced by Wong et al (US5758643) noting col. 2, lines 1-5 where temperature sensors are used in conjunction with glucose sensors so that various parameters of the blood are simultaneously determined. In view of Wong et al (US5758643), it would have been obvious to one of ordinary skill in the art to provide a temperature sensor in conjunction with the glucose sensor of the previously described apparatus so that various parameters of the blood are simultaneously determined thereby providing additional analytical information about the patient.

***Other Pertinent Prior Art***

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The art should be both separately considered and considered in conjunction with the previously cited prior art when responding to this action. GB 267, GB 081, US 301, US 147 disclose glucose detection systems relevant to the instant invention.

### ***Response to Arguments***

Applicant's arguments have been considered but are deemed to be moot in view of the new grounds of rejection.

### ***Final Rejection***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of



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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Conclusion***

Any inquiry concerning this or earlier communications from the examiner should be directed to John A. Jeffery at telephone number (703) 306-4601 or fax (703) 305-3463. The examiner can normally be reached on Monday-Thursday from 7:00 AM to 4:30 PM EST. The examiner can also be reached on alternate Fridays.

The fax phone numbers for the organization where this application or proceeding is assigned are:

Before Final	(703) 872-9302
After Final	(703) 872-9303
Customer Service	(703) 872-9301

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0861.



**JOHN A. JEFFERY  
PRIMARY EXAMINER**

**5/29/03**